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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/701,680 | 11/29/2000 | Ryuzo Hosotani | YANAGIHARA | 7997 |

7590 06/03/2002

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EXAMINER

WHITE, EVERETT NMN

| ART UNIT | PAPER NUMBER |
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1623

DATE MAILED: 06/03/2002

4

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/701,680

Applicant(s)

HOSOTANI ET AL.

Examiner

EVERETT WHITE

Art Unit

1623

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-6 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:
The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
2. Claims 1-6 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted step is: The claim fails to disclose the final process step that indicates that the aggregates have been formed. Further characterization of the claimed invention is requested. Claims 2-6 are also rejected since these claims do not correct this error.

In Claim 4, line 2, what does the phrase "number of associations" mean. It is not clear in the claim and specification what this phrase is referring to as it regard to 3-20 hydrophobic group-containing polysaccharide molecules.

The parenthesis in Claim 5 should be removed and replace with commas.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation

under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

4. Claims 1-6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shiku et al (WO 98/09650) or Macromolecules, 3062 (1993) in view of Okumura et al (US Patent No. 5,272,053).

Applicants claim a process for forming aggregates of hydrophobic group-containing polysaccharide in water, comprising causing the hydrophobic group-containing polysaccharide to swell in water and treating the resulting swollen dispersion by dispersing it using a homogenizer under a pressure of 9.8 – 490 MPa (100 – 5,000 kgf/cm²).

The instant specification on page 4, 2nd paragraph discloses that the Shiku et al WO patent and the Macromolecules reference disclose processes in which the hydrophobic group-containing polysaccharide is caused to swell in water and the resulting swollen dispersion is then treated by ultrasonication. The process of the instantly claimed invention differs from the process of the Shiku et al patent and the Macromolecules reference because the step of dispersing said swollen dispersion is performed with a homogenizer as opposed to treatment by ultrasonication.

The Okumura et al patent teaches the interchangeability of a homogenizer with an ultrasonicator is well known in the art. See the paragraph bridging columns 25 and 26 wherein the dispersion of a hydrophobic compound in an aqueous solution may be carried out using any number of apparatuses that include a homogenizer and an ultrasonicator. Also see the abstract of the Shiku et al WO patent for the disclosure of a formula of a hydrophobic group that may replace a hydroxyl group of the polysaccharide, which is similar to the hydrophobic group represented by formula (1) of instant Claim 5. The instant claims also specify carrying out the dispersion at a particular pressure. However, it is within the skill of an artisan to adjust the pressure of an apparatus to achieve optimum results. It would have been obvious to one of

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ordinary skill in the art at the time the invention was made to substitute the ultrasonicator used in the Shiku et al WO patent and the Macromolecules reference with a homogenizer, in view of the disclosure of Okumura et al, which teaches and provides as motivation to use a homogenizer as an effective means for dispersing hydrophobic compounds in an aqueous solution, and use of a homogenizer following the procedures set forth in the prior art, renders the instantly claimed process for preparing aggregates prima facie obvious.

Information Disclosure Statement

5. A copy of the references that are disclosed in the instant specification is requested, especially the Macromolecules reference disclosed on page 4, 2nd paragraph of the instant specification.

6. The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609 A(1) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered.

Summary

7. All the pending claims are rejected.

Examiner's Telephone Number, Fax Number, and Other Information

8. For 24 hour access to patent application information 7 days per week, or for filing applications, please visit our website at www.uspto.gov and click on the button "Patent Electronic Business Center" for more information.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Everett White whose telephone number is (703) 308-

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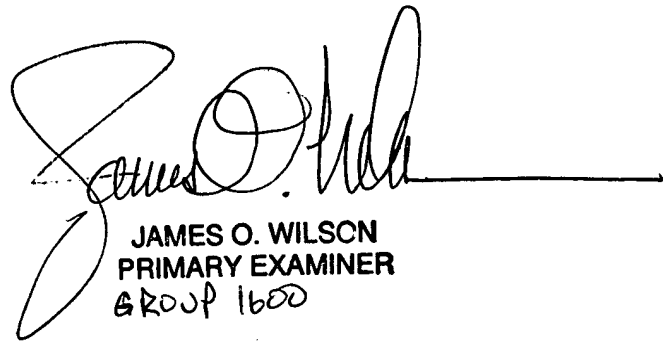
4621. The examiner can normally be reached on Monday-Friday from 9:30 AM to 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann R. Richter, can be reach on (703) 308-4532. The fax phone number for this Group is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-1235.

E. White

E.White


JAMES O. WILSON
PRIMARY EXAMINER
GROUP 1600